OFFICE OF SPECIAL MASTERS

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, Massachusetts for petitioner James A. Reistrup, United States Dep't of Justice, Washington, D.C. for respondent

UNPUBLISHED DECISION¹

On August 12, 2004, Petitioner, Jamie Rollins on behalf of her son Joseph Rollins, filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("the Program"). 42 U.S.C. §§ 300aa-1 et seq. Ms. Rollins alleges that the hepatitis B vaccine, which Joseph received on September 28, 2001, caused him to suffer from optic neuritis. Petition ("Pet.") at 1.

On May 31, 2006, Ms. Rollins filed a Motion for a Ruling on the Record. This motion is GRANTED. The Court finds that the information on the record does not show entitlement to an award under the Program. Petitioner's claim for compensation is hereby DENIED.

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

I. FACTS

Joseph was born on December 1, 1990. Exhibit 1 at 4. His medical history for the next ten years is not significant. He had illnesses typical of childhood. See Exhibit 1 (records of Dr. Rodney Fink). Respondent has not argued that these illnesses affect his claim for compensation. See Respondent's Report, filed December 6, 2004.

As relevant to this case, Joseph's health problems began in the days immediately following the September 11, 2001 attacks. See Exhibit 7 at 12-13 (emergency department note from Mary Washington Hospital, dated October 21, 2001, stating that Joseph "has been sick since 09/11/01. . . . All of these symptoms apparently have come and gone over the last seven weeks since the World Trade Center collapsed when he states this all occurred."); exhibit 7 at 29 (emergency department note from Mary Washington Hospital, dated October 26, 2001, stating that Joseph said his vomiting, headaches and chest pains have been "actually ongoing since the day after the September 11th attacks.") As discussed below, other records indicate that Joseph's health problems started a few weeks later. It is unclear from the records which of Joseph's problems constituted the early symptoms of his ultimate diagnosis.

On September 28, 2001, Joseph received the first dose of the hepatitis B vaccine. Exhibit 2 at 1-2; Exhibit 13 \P 1.

Beginning on October 4, 2001, Joseph saw a series of medical practitioners for various illnesses. First, on October 4, 2001, Joseph saw a nurse at his school. He complained of nausea, headaches and mid abdominal pain. The nurse recommended rest and returned Joseph to the classroom without notifying his parents. Exhibit 2 at 6.

Then, on October 8, 2001, Joseph saw a school nurse five times. He complained about mid-abdominal pain and nausea. He vomited at least twice and had dry heaves. The nurse eventually released Joseph to leave school with his aunt. Exhibit 2 at 6. His aunt brought Joseph to a clinic. The chief complaints were severe headaches, drainage from his nose, and vomiting three to five times per day for a week. The doctor diagnosed left otitis media, allergic rhinitis, and possible depression due to a decrease in friends following a recent move. The doctors prescribed amoxicillin and claritin, and suggested that Joseph follow up with his primary care doctor for his depression. Exhibit 12 at 3.

On October 15, 2001, Joseph again saw the school nurse because he had vomited. Exhibit 2 at 6. The nurse recommended rest and the record does not show any follow up treatment for this incident.

In an affidavit, Ms. Rollins describes Joseph as a "changed child." Exhibit 13 ¶ 3. Although Ms. Rollins's statement is not explicit as to when Joseph "changed," the context of her

statement supports an inference that Ms. Rollins attributes the change in his condition to a time after his vaccination and before his trip to the emergency department.

Joseph went to the emergency department at Mary Washington Hospital on October 21, 2001. Ms. Rollins stated he had been sick since September 11, 2001. Joseph had many complaints, including vomiting, back pain, neck pain, chest pain, and abdominal pain. According to the doctor, Joseph "has had just about every complaint in the multisymptom that one could imagine." The doctor did not "see an acute life-threatening illness" and he suggested that Joseph have an outpatient pediatric evaluation. Exhibit 7 at 12-13. Ms. Rollins recalled that the doctor told her that Joseph was going through puberty. Exhibit 13 ¶ 3.

A few days later, Joseph told his mother that a waitress had a beard. Exhibit $13 \, \P \, 4$. On October 26, 2001, Ms. Rollins brought Joseph to see an optometrist, Dr. Michelle Thelen. Exhibit 3 at 1.

The complaint to Dr. Thelen was "blurry distance vision lately for [approximately] two weeks." Exhibit 3 at 1. After conducting an internal examination, Dr. Thelen detected grade 3+ papilledema. <u>Id.</u> Papilledema is "edema [swelling] of the optic disk (papilla), most commonly due to increased intracranial pressure, malignant hypertension, or thrombosis of the central retinal vein." <u>Dorland's Illustrated Medical Dictionary</u> 1359 (30th ed. 2003). Dr. Thelen directed Joseph to go to the emergency room at Mary Washington Hospital for magnetic resonance imaging ("MRI"), lumbar puncture, and blood work immediately. Exhibit 3 at 1.

At the emergency department, Joseph's problems were described as acute vomiting, headache, and chest pain. These problems began the "day after the September 11th attacks." Exhibit 7 at 29. His fundi, the bottom of his eyes, were "remarkable for marked bilateral papilledema and cotton-wool spots." The doctor also noted that Joseph's neck was stiff. <u>Id.</u> at 30. After receiving negative results on several diagnostic tests, the doctor recommended transfer to Fairfax Pediatric Emergency Department, where Joseph could be seen by a pediatric ophthalmologist and a pediatric neurologist. <u>Id.</u> at 31.

On October 27, 2001, Joseph was admitted to Fairfax Hospital. Exhibit 8 at 8. The complaints included a four week history of headaches, vomiting, neck stiffness, photophobia, and lethargy. Medical personnel also noted that he was diagnosed with papilledema while at Mary Washington Hospital. <u>Id.</u> at 8-9, 18. The attending physician requested consultations from a pediatric neurologist, a pediatric ophthalmologist, and an infectious disease specialist. <u>Id.</u> at 20.

The infectious disease specialist, Dr. Mary Buessing, examined Joseph on October 27, 2001. Her assessment was "encephalitis associated with papilledema." (Encephalitis is an "inflamation of the brain." <u>Dorland's</u> at 608.) Dr. Buessing ordered various tests to try to determine the cause of the encephalitis.

Dr. Sarah Stair, a pediatric ophthalmologist, confirmed the papilledema. She opined that it was causing Joseph's vision problems. Dr. Stair did not offer a theory as to what caused the papilledema. Exhibit 8 at 25.

Joseph also saw a pediatric neurologist, Dr. Bennett Lavenstein, on October 27, 2001. In describing the history of Joseph's illness, Dr. Lavenstein noted that he received the hepatitis B vaccine "before the present symptoms started." Dr. Lavenstein's assessment was that Joseph had "increased intracranial pressure in the setting of an apparent infectious etiology." Dr. Lavenstein ordered various tests to try to determine the cause of the underlying infection. Exhibit 8 at 23.

Although most of the tests showed normal results, two were notable. First, on October 29, 2001 a test completed to detect an enterovirus was positive. Exhibit 4 at 20. Second, on October 27, 2001, the preliminary result of a test to reveal the presence of mycoplasma pneumoniae was a "low positive." Exhibit 4 at 29; Exhibit 8 at 102. When this test was repeated on October 30 and November 1, 2001, the results were "positive." Exhibit 4 at 29. "Because of these results and because of negative results on other serologic tests, the patient was diagnosed with encephalitis, possible mycoplasma etiology." Exhibit 8 at 15 (discharge report, dictated December 19, 2001); accord id. at 44, 45 (note about labs), 51, 54 (note of attending physician stating "Joseph is being treated for encephalitis which is [secondary] to enterovirus / mycoplasma").

On October 28, 2001, Joseph underwent a second lumbar puncture. He had increased intracranial pressure. Exhibit 8 at 39-40. He also complained of blurred vision. <u>Id.</u> at 39. An electroencephalogram, performed on October 30, 2001, was "mildly abnormal." <u>Id.</u> at 2. A consultation with Dr. Preston Calvert, a neuro-ophthalmologist, was requested. <u>Id.</u> at 52.

Dr. Calvert examined Joseph on October 31, 2001. As part of his review of the history of Joseph's problems, Dr. Calvert stated that there is a "recent Hep B immunization as well." Exhibit 8 at 28. Dr. Calvert determined that Joseph suffered from "severe optic neuropathy" in his right eye and a milder neuropathy in his left eye. Joseph also had elevated intracranial pressure associated with meningeal inflammation. Dr. Calvert suggests that the cause might be mycoplasma or post-infection. Dr. Calvert recommended an urgent optic nerve fenestration.

On November 1, 2001, a surgeon completed an optic nerve fenestration. Exhibit 8 at 33. No problems were reported after this procedure. Id. at 57-58.

In a progress report made on November 1, 2001, Dr. Keim, an infectious disease specialist, stated that he is "considering Hepatitis B immunization as a possible etiology." Exhibit 8 at 55. One day before offering this possible explanation, Dr. Keim stated that "I'm not sure that the [positive] mycoplasma is not a red herring. I don't have another good [infectious disease] etiology to put forth." <u>Id.</u> at 51. On November 2, 2001, Dr. Keim's notes indicate "Discussed? role of Hepatitis immunization [with] aunt & mother the other day. I said that

nothing definitive about causation could be said. I said it was not unreasonable to not give any further hepatitis B immunizations." <u>Id.</u> at 59.

Joseph remained in the hospital until November 7, 2001. When he was discharged, he was instructed to follow up with his pediatric neurologists (Drs. Lavenstein and McClintock), neuro-ophthalmologist (Dr. Calvert), and his infectious disease specialists (Drs. Buessing and Keim). Exhibit 8 at 14-16.

Dr. Calvert, the neuro-ophthalmologist, saw Joseph on November 12, 2001. After describing Joseph's current condition, Dr. Calvert offered his views about what caused the optic neuropathy. "The mechanism of his increased intracranial pressure appears to be a parainfectious meningitis with increased intracranial pressure. There is evidence by serology of Mycoplasma pneumonia infection." Dr. Calvert's analysis does not end here. He continues by at least implying another potential cause: "Because there was some temporal association with hepatitis B immunization, I recommended avoiding the rest of this immunization sequence." Exhibit 4 at 8.

Dr. Keim, the infectious disease specialist, saw Joseph on November 14, 2001. Dr. Keim described that he was uncertain as to what caused Joseph's problems:

I had a lengthy talk with the family with regards to etiology. I said that we frankly didn't know. We noted the hepatitis B immunization that he had six days before becoming ill and I said that the association was there but whether it was causal could not be told. Similarly, I said that we were suspicious about the mycoplasma but there were some questions about antibody responses. . . . The bottom line was that I said we didn't know. I did give the family a letter exempting Joseph from further Hepatitis B immunizations. I also gave them a letter suggesting it would be prudent not to immunize his siblings with Hepatitis B either.

Exhibit 4 at 6.

On November 26, 2001, Joseph saw his third specialist after being discharged from the hospital. Dr. McClintock, a pediatric neurologist, found that Joseph was generally improved. Dr. McClintock did not offer any theories as to what caused Joseph's problems. Exhibit 4 at 3-4.

Joseph continued to see various doctors. He saw Dr. Calvert again on March 29, 2002. Dr. Calvert reported that Joseph "has had a complete resolution of his disk swelling." Dr. Calvert noted that Joseph lost some visual field in his right eye. Exhibit 6 at 7.

Although the records indicate that Joseph received medical care for other problems, they do not indicate additional treatment for optic neuritis. Ms. Rollins does not identify any ongoing treatment for Joseph in her petition.

II. PROCEDURAL HISTORY

Ms. Rollins first filed this petition on August 12, 2004. She then filed Joseph's medical records two weeks later.

Respondent filed its report, pursuant to Vaccine Rule 4, on December 16, 2004. Respondent asserted that the petition should be denied. Respondent argued that the mycoplasma infection caused Joseph's encephalitis, which in turn caused intracranial pressure, which caused papilledema, which caused Joseph's optic neuropathy. Respondent's Report at 15. Respondent argued that Ms. Rollins was required to present "legitimate and reliable scientific evidence" showing that the hepatitis B vaccination caused Joseph's problems. Id. at 16.

The special master to whom this case was initially assigned conducted a status conference on May 18, 2005. In this status conference, Ms. Rollins represented that she was attempting to retain a treating doctor as an expert witness and was also attempting to retain another expert witness. Following this status conference, the special master ordered that Ms. Rollins provide status reports describing progress on obtaining an expert's report every 30 days. Order, filed May 19, 2005.

Almost one year later, Ms. Rollins filed a status report indicating that her attorney received a preliminary opinion from a pediatric neurologist. The attorney requested 30 days to discuss this report with Ms. Rollins. Petitioner's Status Report, filed April 28, 2006.

Ms. Rollins was ordered to submit her expert's report or a status report by May 31, 2006. Order, filed May 4, 2006. On that date, without submitting an expert's report, Ms. Rollins submitted a motion for judgment on the record.

III. ANALYSIS

To receive compensation for Joseph's condition under the Program, Ms. Rollins must prove either: (1) that Joseph suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or (2) that Joseph suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec'y of Health and Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, Ms. Rollins does not claim that Joseph suffered a table injury. Thus, she must prove causation in fact.

A petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record. 42 U.S.C. § 300aa-13(b)(1). This universe necessarily includes "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the petitioner's illness." 42

U.S.C. § 300aa-13(b)(1)(A). Here, because the medical records do not seem to support Ms. Rollins's claim, a medical opinion must be offered in support. Ms. Rollins, however, has offered no such opinion.

The records are sufficiently developed that a decision made be made as to whether Ms. Rollins is entitled to a Program award. See 42 U.S. C. § 300aa-12(d)(3)(B)(v); Vaccine Rule 8(b).

To prove causation in fact, a petitioner must establish at least three elements. The petitioner's

burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

The records do not support a judgment in favor of Ms. Rollins because she has failed to establish any of the three prongs required by <u>Althen</u>.

By medical records or by medical opinion, Ms. Rollins has failed to establish the first prong of <u>Althen</u> – "a medical theory causally connecting the vaccination and the injury." As mentioned, Ms. Rollins has not presented the opinion of an expert. Thus, she must rely upon the opinions of treating doctors contained in the medical records.

The medical records do not contain a "medical theory." Viewed in the light most favorable to Ms. Rollins, the medical records show that some doctors noted that the hepatitis B vaccination occurred before Joseph began displaying symptoms. See Exhibit 8 at 23, 28. However, temporal association standing alone does not constitute a "medical theory." Grant v. Sec'y of Health and Human Servs., 956 F.2d 1144, 1148 (Fed. Cir.1992) (citing Hasler v. United States, 718 F.2d 202, 205 (6th Cir.1983)).

Even the doctor's reports that recognize an association between the hepatitis B vaccination and the development of encephalitis, merely discuss the causal connection as a possibility. Exhibit 8 at 55, 59 (Dr. Keim stating "that nothing definitive about causation could be said."); Exhibit 4 at 6 (Dr. Keim stating whether the vaccination "was causal could not be told.").

A "possibility" cannot establish a medical theory. Van Epps v. Sec'y of Health and Human Servs., 26 Cl. Ct. 650, 654 (1992); Doe v. Sec'y of Health and Human Servs, 19 Cl. Ct. 439, 450 (1990) ("an assertion that something is 'highly possible' does not rise to the level necessary to establish causation by a preponderance of the evidence"); Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation does not establish a probability); Duncan v. Sec'y of Heath and Human Servs., No. 90-3809V, 1997 WL 75429, at *4 (Fed. Cl. Spec. Mstr. Feb. 6, 1997) ("The court notes further that [petitioner's expert] is unwilling to state his opinion to a reasonable degree of 'medical probability' but as 'a possibility' only, a standard that cannot support a finding of a preponderance of evidence."); Lacour v. Sec'y of Heath and Human Servs., No. 90-316V, 1991 WL 66579, at * 5 (Cl. Ct. Spec. Mstr. Apr. 15, 1991) ("Expert medical testimony which merely expresses the possibility – not the probability – of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred.").

Furthermore, Ms. Rollins has failed to establish the second prong of <u>Althen</u> – a logical sequence of cause and effect. Again, because Ms. Rollins did not present an expert opinion, her evidence must be found in the medical records.

The records explain that Joseph's vision troubles were caused by pappiledema and that the papilledema was caused by intracranial pressure and that the intracranial pressure was caused by encephalitis. Exhibit 5 at 5. This chain of causation stops here, one step short. The medical records do not contain any statement, expressed with the requisite degree of certainty, that the hepatitis B vaccination caused the encephalitis.

Finally, Ms. Rollins failed to establish the third prong of <u>Althen</u> – an appropriate temporal relationship between vaccination and the onset of Joseph's illness. Because proof for the first two prongs was lacking, it follows that the record does not contain any information about what is an appropriate interval.

Furthermore, although this point is ancillary, the record is not clear when Joseph's encephalitis began. Some records indicate that he had headaches, was vomiting, and had chest pains following the September 11th attacks. Exhibit 7 at 12-13, 29. No doctor has explained whether these problems were early signs of encephalitis. If they were linked to encephalitis, the encephalitis would predate the vaccination. If so, the vaccination could not have caused the encephalitis, although the vaccination may have aggravated it.

Judgment cannot be granted in petitioner's favor without resolving when Joseph's encephalitis began. The parties appear to have assumed that Joseph did not have any pre-existing condition when he received the hepatitis B vaccination. See Order, dated May 19, 2005. Even with this assumption, which is an assumption in favor of Ms. Rollins, she has failed to meet each of the three elements that Althen requires for proving causation in fact.

IV. <u>CONCLUSION</u>

For these reasons, petitioner's claim for compensation is hereby DENIED. In the absence of a motion for review, the Clerk of the Court shall enter judgment dismissing the petition.
IT IS SO ORDERED.

Christian J. Moran Special Master